

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

GEDULIN, B. et al.

Appl. No.: 10/671,304

Filed: September 24, 2003

For: TREATMENT OF PANCREATITIS
WITH AMYLIN

Confirmation No.: 8486

Art Unit: 1655

Examiner: WINSTON, Randall O.

Atty. Docket: 0101US-UTL

Declaration of Steve Chen, M.D.

1. I am presently employed as a Director of Medical Affairs with Amylin Pharmaceuticals, Inc. in San Diego, California. Amylin Pharmaceuticals, Inc. focuses on the research, development, and commercialization of peptide-based drug compounds, specifically in the area of the treatment and management of diabetes and other glucose metabolism disorders. Amylin Pharmaceuticals, Inc. is also the assignee of the captioned case. I hold an M.D. from Albert Einstein College of Medicine. Subsequent to medical college I completed residency training in Internal Medicine at Scripps Clinic and a subspecialty fellowship in nutrition and metabolic diseases. I have also worked as an emergency room attending physician supervising residents at West Los Angeles Veteran's Affairs Hospital for four years. I am an author on five peer-reviewed papers in the fields of metabolism. I have four years of experience as a junior faculty metabolic diseases and an additional one year of experience in the capacity of director in the biotechnology and pharmaceutical industries, focusing mostly on diabetes and obesity.

2. I understand that the present case deals with the treatment of pancreatitis, and that the Examiner in the case has alleged that treatment of pain is inherently treatment of the underlying pancreatitis.

3. When considering pancreatitis, it is important to realize that there are two major categories of pancreatitis. The first type of pancreatitis is "acute pancreatitis," which occurs suddenly when digestive enzymes produced in the pancreas remain in the pancreas and become

active, irritating and inflaming pancreatic tissue (normally digestive enzymes are transported to the duodenum, and become active there).

4. The other type of pancreatitis is “chronic pancreatitis,” which differs from acute pancreatitis in that the inflammation happens over a period of years and can cause permanent damage to the pancreas. Chronic pancreatitis is usually less obvious than the acute form, and in its early stages can be difficult to recognize. In many cases people with chronic pancreatitis have no pain or other symptoms. Other people have intermittent periods of mild to moderate abdominal pain or nonspecific gastrointestinal symptoms. As inflammation persists in these cases, it can slowly destroy the pancreas. Unfortunately, the pain accompanying chronic pancreatitis usually lessens as the condition progresses and worsens, apparently because the pancreas is no longer making digestive enzymes. This is unfortunate because the afflicted person might assume that with the lessening of pain the condition is improving. Additionally, chronic pancreatitis often causes no symptoms and many times is discovered by accident during the course of investigating symptoms not related to pancreatitis (e.g. calcification of the pancreas may be seen on an x-ray of the abdomen performed for other reasons). Thus, a number of people suffering from chronic pancreatitis will have no pain and thus have no motivation to seek treatment or pain relief.

5. For this reason, the mere treatment of pain caused by pancreatitis is not a treatment of the underlying pancreatitis, because the pain and the pancreatitis do not always overlap. It is often the case that a pancreatitis is present that would require treatment, but is not causing a discernible or problematic pain to the patient. Thus, one would not expect such a patient to be taking or have a need for analgesics. Furthermore, a patient being treated for pain caused by pancreatitis would generally be prescribed conventional pain relievers (e.g. panadol), not a medication requiring injection for administration.

6. In the treatment of pain, the most common starting point is with oral therapy if patients can tolerate orals. However some patients with severe pancreatitis are unable to take orals due to the nausea associated with the pancreatitis and other delivery forms such as subcutaneous or intravenous would need to be considered. Thus, a medication like amylin is not something that would ordinarily be prescribed for pain caused by pancreatitis. However, I also

note that morphine is administered in injectable form for relief of severe pain caused by pancreatitis in cases where a powerful pain reliever is warranted and where no more convenient alternative is available.

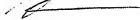
7. In those cases where pancreatitis causes significant pain, a patient would administer a pain killer during times necessary to relieve pain, and discontinue administration of pain killer when pain ceases. Thus, pain killers are not necessarily administered throughout the course of treating pancreatitis. And in those cases where the patient is not experiencing significant pain, no pain reliever would be administered.

Closing

To the best of my knowledge all statements made herein are true and correct. I make this statement with the understanding that willfully making a false statement in this context is punishable under 18 U.S.C. § 1001 by fine, imprisonment, or both.

Respectfully submitted,

Date: June 26, 2009

By: 
Steve Chen, M.D.